

## **REMARKS/ARGUMENTS**

This is in response to the Office Action mailed January 3, 2006.

Claims 1 and 14 have been amended. Support for amendments to claims 1 and 14 can be found throughout the originally filed application, e.g., paragraphs 25 and 26. No new matter is introduced and these are not intended to be narrowing amendments. Independent claim 1 and its dependent claims 2-9 and 14-18, independent claim 10 and its dependent claims 11-13, and independent claim 19 and its dependent claims 19-22, are currently pending and at issue.

### **Claim Rejections - 35 U.S.C. §103**

The Examiner has rejected the claims under U.S.C. § 103(a) as being unpatentable over (1) Metz et al (AJH 1:58-60 1988), (2) Skinner (Scan J Nutr 2/99 suppl 34 p. 45S), and (3) Summerbell (BMJ 317 1998 p. 1478-89), in view of knowledge that allegedly can be obtained by routine experimentation or is well known to one of ordinary skill in the art.

In each of the three rejections, the Examiner has not established a *prima facie* case of obviousness. Each cited reference does not teach or expressly or impliedly suggest any of the limitations set forth in the present claims. There is no motivation to combine the references with other knowledge. There would not be a reasonable expectation of success. Moreover, it is inappropriate for the Examiner to take official notice that elements can be readily obtained by routine experimentation or are generally known to one of ordinary skill in the art, so as to modify the references to reach the claimed invention.

In addition, the Applicants are submitting evidence showing the present invention's unexpected results, which has led to a significant shift in the scientific community and the food industry, which has supported and endorsed the methods of the present invention leading to significant recognition and commercial success.

The Examiner has rejected claims 1-8, 10-14, 16, 17, and 19-21 under U.S.C. § 103(a) as being unpatentable over Metz et al (AJH 1:58-60 1988). The Examiner asserts that Metz teaches a reduction in body fat in rats consuming higher diets of calcium and that it would have been obvious to one of ordinary skill in to formulate a high calcium diet for humans to achieve the beneficial effect of a reduction in body fat content in view of the Metz results.

Independent claims 1, 10 and 19 are directed to methods for administering therapeutically effective or sufficient amounts of calcium or dairy in an individual regulating body weight to induce weight loss, prevent weight gain, and/or increase the metabolic consumption of adipose tissue, or induce a metabolic change in the individual.

The present invention is distinct from Metz, which does not disclose, teach or suggest any of the elements of independent claims 1, 10 or 19. Metz is directed to a hypothesis that modification of body fat can be accomplished by the simultaneous administration of calcium with sodium. In the introduction, Metz teaches that some reports indicate supplementation of both dietary calcium and sodium results in a beneficial interaction between these two cations. The experiments were conducted on rats in three groups receiving: (1) high calcium/ high sodium, (2) moderate calcium/ moderate sodium and (3) low calcium/ low sodium. The results show that groups receiving higher amounts of calcium and sodium resulted in body weight reductions.

As set forth in the discussion, Metz teaches that "[t]o date,  $\text{Ca}^{2+}$  intervention trials in humans with hypertension have not noted significant reduction in body weight with  $\text{Ca}^{2+}$  supplementation." Metz further teaches that: "[d]ietary sodium was simultaneously modified in this study, as earlier investigations had demonstrated that calcium effects on blood pressure were, in part, sodium-dependent. Thus, concurrent manipulations of  $\text{Ca}^{2+}$  and  $\text{Na}^+$  were utilized in this study." Metz concludes that "current results confirm that body fat and weight can be favorably

modified by increasing the dietary content of both calcium and sodium."

Metz uses both "calcium and sodium" to show body weight changes. Metz does not isolate calcium from sodium and does not show or suggest that specifically only calcium or dairy is responsible for the weight benefits. Nor could or would one be motivated to separate the effects of calcium from sodium because that was not part of the hypothesis of Metz, relating to the synergistic effects of calcium with sodium on body fat and weight. To the contrary, the present invention specifically shows that calcium alone, without sodium, induces weight loss. Indeed, the use of two elements to affect body weight as in Metz, in contrast to the omission of one (sodium), while still retaining the function of weight loss as in the present invention, supports unobviousness of the present invention. See MPEP § 2144.04 ("the omission of an element and retention of its function is an indicia of unobviousness").

Therefore, Metz does not teach or suggest the use of calcium or dairy to induce weight loss, prevent weight gain, and/or increase the metabolic consumption of adipose tissue, or induce a metabolic change in an individual regulating body weight as set forth in the present invention.

The Examiner further asserts that as to the particular dosage frequency, amount and vehicle, optimum parameters may be obtained by routine experimentation. This is incorrect because even with hindsight analysis, it would take extensive experimentation to obtain the dosage frequency, amount and vehicle as required by the present invention. The specification reflects extensive experimentation to show the effects of calcium and dairy to induce weight loss, prevent weight gain, and/or increase the metabolic consumption of adipose tissue, or induce a metabolic change in an individual regulating body weight. For example, Example 1 involved at least six weeks of administration and Example 2 involved at least two six-week stages, all of which were followed by extensive analysis to arrive at the inventive methods. This is evidence

that undue experimentation would have been required.

Also, the Examiner contends that one of ordinary skill will recognize that reduction in body fat content is a consequence of lipolysis of fat in adipocytes. However, one would not be motivated to combine the teaching of Metz with this consequence because the benefits of calcium alone or dairy was not previously recognized and would have been unexpected at the time the application was filed to induce weight loss, prevent weight gain, and/or increase the metabolic consumption of adipose tissue, or induce a metabolic change in an individual regulating body weight.

Moreover, the Examiner inappropriately takes official notice without documentary evidence to support the above conclusions. Official notice unsupported by documentary evidence should not be taken by the Examiner because the facts are not capable of instant and unquestionable demonstration as being well-known, and are in dispute (MPEP § 2144.03). As demonstrated by evidence submitted by the Applicant, as discussed below, the results of this invention, at the time the application was filed, were unexpected. For example, it would not have been commonly known to use calcium, calcium containing product, and dairy to induce weight loss. Therefore, official notice as set forth by the Examiner that the claimed invention is obvious over allegedly well known elements is not permissible under these circumstances.

Claims 1-8, 10-14 and 17-21 were rejected under U.S.C. § 103(a) as being unpatentable over Skinner (Scan J Nutr 2/99 suppl 34 p. 45S). The Examiner contends that Skinner teaches that children's body mass is moderated by dietary calcium and that it would have been obvious to one of ordinary skill to formulate a high calcium diet for children to achieve the beneficial effect of a reduction in body fat content in view of Skinner.

The present invention is distinct from Skinner, which does not disclose, teach or suggest

the elements of independent claims 1, 10 or 17. Skinner discloses that "[i]n a longitudinal study of healthy children (n=72), three days of food intake were collected at each of six interviews (ages 24 to 60 month) and the longitudinal intakes were determined for various nutrients...". This was done "to determine the role of various nutrients in fat mass." Skinner mentions several variables, including calcium, protein, fat and monounsaturated fat and concludes that "calcium and monounsaturated fat were negatively related to children's fat mass."

However, Skinner does not conduct experiments using calcium or dairy alone, nor was it a weight loss study. The results of Skinner are not based on experiments designed to isolate the effectiveness of calcium or dairy to induce weight loss, prevent weight gain, and/or increase the metabolic consumption of adipose tissue, or induce a metabolic change in an individual regulating body weight, as set forth in the present invention. Instead, Skinner observed intake of various nutrients by children and their fat mass, not weight loss. The children's fat mass could have been affected by a number of variants, e.g., the natural growth of the child based on their genetic makeup, physical activity or other dietary habits. Moreover, Skinner was not directed to individuals regulating body weight, but instead observations of dietary intake in growing children. Growing children are expected to gain weight, not lose weight. One could not extrapolate from these observations a method of administering calcium or dairy to induce weight loss, prevent weight gain, and/or increase the metabolic consumption of adipose tissue, or induce a metabolic change in the subject.

The reference does not suggest that calcium or dairy alone is inducing weight loss, preventing weight gain, and/or increasing the metabolic consumption of adipose tissue, or inducing a metabolic change in an individual regulating body weight. Rather, the association with monounsaturated fat means that the results would not lead one skilled in the art to conclude

that calcium and dairy can be used alone to induce weight loss, prevent weight gain, and/or increase the metabolic consumption of adipose tissue, or induce a metabolic change in an individual regulating body weight. At the time the application was filed this would have been contrary to commonly known perceptions as discussed below.

The Examiner further asserts that as to the particular dosage frequency, amount and vehicle, optimum parameters may be obtained by routine experimentation. Also, the Examiner states that one of ordinary skill will recognize that reduction in body fat content is a consequence of lipolysis of fat in adipocytes.

As noted above, these points are incorrect, irrelevant to the pending claims and/or it was inappropriate for the Examiner to take official notice without documentary evidence to support these conclusions.

Claims 1-17 and 19-21 were rejected under U.S.C. § 103(a) as being unpatentable over Summerbell (BMJ 317 1998 p. 1478-89). The Examiner asserts that Summerbell teaches weight loss in obese patients on a diet comprising milk or yogurt and that it would have been obvious to one of ordinary skill to formulate a high calcium diet for obese patients to achieve the beneficial effect of a reduction in body fat content in view of the Summerbell.

Applicants contend that the present invention is distinct from Summerbell, which does not disclose, teach or suggest any of the elements of independent claims 1, 10 or 19.

As set forth in the introduction, Summerbell tests diets with high compliance and hence good for weight loss. The study in Summerbell was designed to test the hypothesis that prescription of a simple and novel diet would result in higher levels of compliance and weight loss. In fact, Summerbell associates higher weight loss for the milk groups diet because that diet is "simple but much less boring and patients were more likely to comply with it" than with the

conventional diet. Indeed, Summerbell is "not advocating milk only as a general long term reducing diet for obese outpatients, because in the long term it will cease to be novel and compliance will fall." Summerbell concludes that "[p]robably the best strategy is to rotate diets..." These statements would lead one away from the teaching of the present invention, which involves the use of sufficient amounts of dietary calcium or dairy, e.g., monthly. The point to extrapolate from Summerbell is that one could use any type of food regimen or diet so long as it is simple and less boring to ensure compliance. Nowhere in Summerbell is it disclosed that calcium or dairy directly induces weight loss, prevents weight gain, and/or increases the metabolic consumption of adipose tissue, or induces a metabolic change in an individual regulating body weight, as opposed to indirectly causing a dieter to lose weight by reducing overall caloric intake.

The Examiner further asserts that as to the particular dosage frequency, amount and vehicle, optimum parameters may be obtained by routine experimentation. Also, the Examiner states that as to the calcium, it is well known, even to the layman, that dairy products contain calcium and that one of ordinary skill will recognize that reduction in body fat content is a consequence of lipolysis of fat in adipocytes.

As noted above, these points are incorrect, irrelevant to the pending claims and/or it was inappropriate for the Examiner to take official notice without documentary evidence to support these conclusions.

The present claims should not be deemed obvious in light of any of the cited references, Metz, Skinner or Summerbell, because none of the cited references expressly or impliedly teach, disclose or suggest, any of the limitations set forth in present claims 1, 10 or 19. Moreover, there is no motivation to use the cited knowledge, nor would combining the cited references or

knowledge teach the claimed methods of administering therapeutically effective or sufficient amounts of calcium or dairy to induce weight loss, prevent weight gain, and/or increase the metabolic consumption of adipose tissue, or induce a metabolic change in an individual regulating body weight.

Prior to the invention recited here, there was no recognition that calcium in food products or dairy would be beneficially or therapeutically effective to induce weight loss, prevent weight gain, and/or increase the metabolic consumption of adipose tissue, or induce a metabolic change in an individual regulating body weight. The importance of maintaining high calcium intake and dairy during attempts to lose, maintain or control weight in an individual regulating weight was previously unrecognized and was unexpected and contrary to general knowledge prior to Dr. Zemel's team's pioneering work.

Due to these unexpected results, there has been a significant shift in the scientific community and the food industry, which has supported and endorsed the methods of the present invention. The inventive methods have achieved considerable public recognition and commercial success, as indicated by the attached documentation.

Page one of the attached material lists various clinical trials conducted by Dr. Zemel's team and others further showing the beneficial effects of consuming high calcium and dairy in accelerating the effects of weight loss in humans. Page two shows how the food industry has adopted the novel communication methods of the present invention. For example, the label "3-A-Day Milk Cheese Yogurt, Burn more fat, lose weight" communicates the message that increasing dairy consumption to at least three servings a day supports weight loss. As set forth on page two, over 50 top U.S. retail chains have licensed the inventive methods and are promoting the inventive methods by placing labels with the weight loss message on over 2.5 billion dairy packages to date.

Pages three, four and five evidence various examples of leading industry packages and consumer advertisements. Page six provides testimonials about the inventive methods from notable health professional associations. The American Academy of Family Physicians refers to "dairy nutrition and its contribution to weight management." The National Medical Association recognizes that "[s]ome of the information that was presented today shows a clear beneficial relationship between the daily intake of three to four servings of dairy products and the reduction of obesity." The American Dietetic Association praises Dr. Zemel's work in that "[i]t has been exciting to see how emerging research on the role of calcium and dairy products adds to the body of knowledge about preventing and treating obesity [and t]his information provides additional tools for dietetics professionals to use in their day-to-day practice."

Applicants further contend that even with widespread recognition, the claimed method is so unexpected that there remains skepticism about communicating the effects of calcium/dairy on weight loss. For example, there have been advertisements asserting that Yoplait yogurt promotes weight loss (advertising claims that are subject to a license agreement under the present patent application). A challenge was filed by an anonymous party, who argued that there was no support for the claim that calcium consumption promotes weight loss. The challenger apparently doubted the efficacy of the invention as claimed in the present application. The National Advertising Division (NAD) of the U.S. Better Business Bureau ruled that the evidence (research by Dr. Zemel) supported General Mills' advertisement of the weight loss benefits of the calcium-containing dairy product (decision attached). This dispute, and its conclusion accepting the surprising evidence of the weight loss efficacy of calcium, further evidences the non-obviousness of the claimed invention. See also Express Article, published by Express Publications, a subsidiary of the Washington Post Company, 7/19/05, p. 10.

Therefore, Metz, Skinner, or Summerbell, either alone or in combination with other knowledge, do not disclose, teach or suggest the claimed invention as set forth in claims 1, 10 or 19 or dependent claims 2-9, 11-18 and 20-22. These include additional limitations distinguishing them from the cited references, e.g., in claim 2, wherein dietary calcium is administered daily in an amount of at least about 1000 mg/day; in claim 3, wherein the method further comprises informing the individual that consumption of the calcium-containing product can induce weight loss or reduce weight gain; in claim 4, wherein the method further comprises determining dietary calcium consumption of the individual and (1) if the dietary calcium consumption is below 1000 mg/day, increasing the dietary calcium consumption, and (2) if the dietary calcium consumption is at least about 1000 mg/day, maintaining the dietary calcium consumption; in claim 5, wherein the amount of dietary calcium consumed by the individual before administering the sufficient amount of calcium-containing products is less than about 400 mg/day; in claim 6, wherein the amount of dietary calcium consumed by the individual before administering the sufficient amount of calcium-containing products is less than about 773 mg/day; in claim 7, wherein the daily calcium administered is at least about 1346 mg/day; in claim 8, wherein the individual is on a calorie restricted diet; in claim 9, wherein the calcium is contained in dairy products; in claim 11, wherein the dairy products are consumed daily; in claim 12, wherein the method further comprises determining the dairy consumption of the individual and (1) if the dairy consumption is below about 57 servings/month, increasing the dairy consumption, and (2) if the dairy consumption is at least about 57 servings/month, maintaining the dairy consumption; in claim 13, wherein the amount of dairy consumed by the individual prior to administering the sufficient amount is less than about 57 servings/month; in claim 14, wherein the calcium consumption induces a metabolic change selected from the group consisting of decreasing intracellular calcium

concentrations ( $[Ca^{2+}]_i$ ), stimulating lipolysis, inhibiting lipogenesis, increasing the expression of white adipose tissue uncoupling protein 2 (UCP2), reducing serum insulin levels, thermogenesis, and decreasing the levels of calcitrophic hormones; in claim 15, wherein the calcium is contained in milk, yogurt, and/or cheese; in claim 16, wherein the calcium is contained in a dietary supplement, foodstuffs supplemented with calcium, or other foods high in calcium; in claim 17, wherein the calcium is contained in a liquid supplemented with calcium; in claim 18, wherein the method further comprises the administration of effective amounts of dairy products, wherein the individual is a child, and the method reduces the risk of adiposity and/or controls weight gain products; in claim 20, wherein the metabolic change occurs within adipocytes; in claim 21, wherein the metabolic change comprises decreasing intracellular calcium concentrations ( $[Ca^{2+}]_i$ ), stimulating lipolysis, inhibiting lipogenesis, and increasing the expression of white adipose tissue uncoupling protein 2 (UCP2); and in claim 22, wherein the metabolic change comprises reducing serum insulin levels, thermogenesis, and decreasing the levels of calcitrophic hormones.

Claims 1-22 are patentable because none of the cited references or material disclose, teach or suggest the present invention.

#### **Double Patenting Non-statutory Rejection**

Claims 1-22 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-66 of prior U.S. Patent No. 6,384,087. To expedite prosecution of the application, Applicants submit herewith a terminal disclaimer in compliance with 37 CFR 1.321(c), to overcome the rejection.

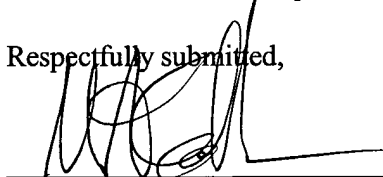
### Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance indicating the allowability of claims 1-22 and that the application be passed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

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Respectfully submitted,



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